REMARKS

Applicant has amended claim 1. Claims 14-19, 23 and 25 have been withdrawn as being drawn to non-elected subject matter. These amendments have been made to place them in better form for examination and to further obviate the 35 U.S.C. §112 rejections as set forth in the Office Action dated July 2, 2003. It is believed none of these amendments constitute new matter. It is submitted that these amendments obviate the rejections. Withdrawal of these rejections are requested.

The Examiner has rejected claims 1 and 8 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Examiner cites *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir.1997) to support this rejection. Applicants note that *Eli Lilly* specifically states that the application of the holding in the case is very fact-specific. Specifically, Applicants note that the court in *Eli Lilly* stated,

> Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "**such descriptive means as words**, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Eli Lilly, 119 F.3d at 1566, 43 U.S.P.Q.2d at 1404 (emphasis added). *See also*, *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). Thus, **words** alone are sufficient to describe the invention. The present specification clearly uses the claimed limitations and thus describes them by words, which meets the requirements of *Eli Lilly*.

Applicants have set forth such a description in words, structures and formulas in the present application. Specifically, the protein is described on the basis of structure, i.e., it is a derivative of a protein consisting of amino acids of SEQ ID NO: 4. This

protein has a structure defined by its amino acid sequence and also is a formula, i.e., a contiguous arrangement of amino acids to form the protein molecule. Alternatively, the protein is one which has at least 75% identity with the protein of SEQ ID NO: 4. Such a protein is described by words. See pages 15 - 17, which discusses the C3H protein and C3H polypeptide. Thus, the application provides a structure of the proteins and a function of the proteins. Thus, it is submitted that the application provides a written description of a protein derivative as set forth in the claims. *Lockwood*, *supra*.

In addition, the term "at least 75% identity", i.e., **words**, is well known in the art and skilled artisans know what these **words** encompass, i.e., a nucleic acid or protein which has a sequence that is at least 75% identical to the reference nucleic acid or protein. This fact is evidenced by many patents which likewise use such **words** to provide a description of their inventions. For example, such patents use similar words to "at least 75% identity" in claiming and disclosing the invention. Since Applicants have described their invention using "**such descriptive means as words**," it is submitted that the specification clearly demonstrates that the inventors were in possession of the claimed invention. *Eli Lilly*. Thus, it is submitted that the specification provides an adequate written description of the invention.

In addition, according to the Written Description Guidelines (*Guidelines for Examination of Patent Applications Under 35 U.S.C. § 112, ¶ 1 Written Description Requirement*, 66 Fed. Reg. 1099 (June 5, 2001)), a patent specification must describe the invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Possession of the claimed invention is shown by describing the claimed invention with all of its limitations, using such descriptive means as **words**, structures, figures, diagrams, and formulas that fully set forth the claimed invention (emphasis added). Possession may be shown in a variety of ways, including description of an actual reduction to practice. An adequate written description may be shown by any description of sufficient, relevant identifying characteristics so long as a person skilled in the art would recognize that the inventor

had possession of the claimed invention.

In the present application, Applicants have clearly conveyed to a skilled artisan what was intended and what was invented. Applicants described **by words** a protein which is a C3H protein with activity in the lignin pathway. Thus, a skilled artisan can readily recognize that Applicants were in possession of the claimed protein.

Furthermore, the Written Description Guidelines permit a description in terms of "functional characteristics when coupled with a known or disclosed correlation between function and structure." The protein of claim 1 has the activity in the lignin pathway. This activity is correlated with the sequence of the protein, i.e., the structure of the protein. Thus, the functional characteristic of the protein coupled with the structure of the protein provides a written description of the invention in compliance with the Written Description Guidelines. Also, the written description as filed is presumed to be adequate, and the Examiner has the burden of providing "sufficient evidence or reasoning as to the contrary...to rebut the presumption [,]...presenting by a preponderance of evidence why a person skilled in the art would not recognize in the applicant's disclosure a written description of the invention defined by the claims." MPEP § 2163.04, citing *In re Wertheim*, 541 F.2d 257, 262-3, 191 U.S.P.Q.2d 90, 96-97 (C.C.P.A.1976). For all of the above detailed reasons, it is submitted that the Examiner has not met this burden.

Since the claimed invention can be described in the application by words and structures, it is submitted that the application is not required to describe the purification and characterization of a protein derivative. *Lockwood, supra*. Thus, it is submitted that a skilled artisan would reasonably conclude that Applicants were in possession of the claimed invention at the time of filing, and therefore the application provides an adequate written description of a protein derivative as set forth in the claims. *Vas Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d ,1111 1116 (Fed. Cir. 1991); *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (CCPA 1981); *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA 1976).

In view of the above remarks and in view of the high level of skill and knowledge in the art, the structure of the protein which is the basis of the homologs or orthologs, the biological and functional characteristics of the proteins and methods for obtaining and making the proteins, it is submitted that the application clearly demonstrates that Applicants were in possession of the claimed invention at the time of filing. Withdrawal of this rejection is requested.

The Examiner rejected claims 1 and 8 under 35 U.S.C. § 112, first paragraph for lack of enablement.

Applicants submit that the enablement standard is an objective one. Thus, as long as there is sufficient guidance provided in the specification of how to make and use the invention, the requirement is met. Also, it is respectfully submitted that there is a presumption that an allegation of enablement of the claimed invention in the specification is correct. *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971). The specification contains a thorough discussion of the expression of the mutant *ref8* sequence in plants at pages 28 - 34. One of ordinary skill in the art of molecular biology will readily recognize that the techniques described therein can be readily applied to other sequences in plants.

Prominent factors that are to be considered in a determination as to whether there is sufficient evidence to support that a disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the art, (6) the relative skill of those in the art, (7) the predictability or unpredictability, and (8) the breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). *See also*, MPEP §2164.01.

The Examiner cites Hu *et al.* to support the allegation that altering lignin content or lignin structure by transforming plants with genes known to be involved in lignin

biosynthesis produces unpredictable results.

Accordingly, Applicants respectfully submit that Hu *et al.* does not support the Examiner's contention that the relevant art is unpredictable. Importantly, the portion of Hu *et al.* that Examiner cites to support his position refers to references dated between 1994 and 1998. The subject application claims priority to a filing date of August 16, 2000. Hu *et al.*, published in August 1999, in fact states, at page 808, left column, 2nd paragraph, that "Significant progress has been made in recent years toward an understanding of lignin biosynthesis (Fig. 1) through characterization of lignin biosynthetic pathway enzymes and genes from both herbaceous and tree crops. At best, Hu *et al.* does demonstrate that some experimentation might be required to make the claimed invention. However, there is no indication that this experimentation would be undue.

The Examiner also cites Franke, R. *et al.* for the proposition that the pathways for lignin in plants are not clearly delineated and the models that have been developed are open to interpretation. Although not conceding this point, even if Examiner is correct in his position, Applicants respectfully submit that the experimentation is not undue to determine if a given sequence alters "the content or composition of lignin in a plant" as claimed in claim 1. The methods for determining the content or composition of lignin in plants are well-known to those of ordinary skill in the art. As discussed above, the specification contains a thorough discussion of the expression of the mutant *ref8* sequence in plants at pages 28 - 34. One of ordinary skill in the art of molecular biology will readily recognize that the techniques described therein can be readily applied to other sequences in plants. Thus, the only experimentation required, which is not undue, is the expression of a given sequence in the plant and a determination of whether or not the content or composition of lignin in the plant is altered.

Accordingly, Applicants submit, even if the art involved were, as the Examiner alleges, unpredictable, which Applicants deny, the specification provides sufficient direction and guidance of how to make and use the invention.

Applicants respectfully submit that the above supports that any experimentation needed in context of the invention claimed in claims 1 and 8 will not be undue.

In view of the above remarks, it is submitted that claims 1 and 8 are fully enabled by the specification. Withdrawal of this rejection is requested.

The Examiner has rejected claims 1 and 8 under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 1 is cited as being indefinite in its recitation of "complement" because it may read upon a single nucleotide. Applicants have amended claim 1 as suggested by the Examiner by insertion of the phrase "full length" before the term "complement." The Examiner states that, in Claim 1, it is not clear whether the amount of lignin is to be increased or decreased or if some unspecified property of lignin is to be enhanced or diminished. Applicants direct the Examiner to the definitions found on page 11 of the specification for "altered lignin content." The Examiner states that the term "ortholog" is indefinite in Claim 1, as there is no definition for this term in the specification. Applicants assert that the term "ortholog" is a term well-known to those of ordinary skill in the art of molecular biology and, therefore, no definition needs to be provided in the specification. The Examiner notes that there is insufficient antecedent basis for "fragment thereof" at line 10 of Claim 1 Applicants have amended the claim to insert the article "a" preceding the phrase "fragment thereof."

Withdrawal of these 35 U.S.C. §112, second paragraph, rejections are requested.

Claims 1 and 8 are rejected under 35 U.S.C. §102(b) as anticipated by Chiang, V. *et al.* Although not conceding that Claims 1 and 8 are anticipated by Chiang, V. *et al.*, Applicants have amended claim 1 to state 84%, which obviates this rejection since Chiang, V. *et al.* has only 83.2% sequence identity to SEQ ID NO: 4.

Withdrawal of this 35 U.S.C. §102(b) rejection is requested.

In view of the above amendments and remarks, it is submitted that the claims satisfy the provisions of 35 U.S.C. §§102 and 112 and. Reconsideration of this application and early notice of allowance is requested.

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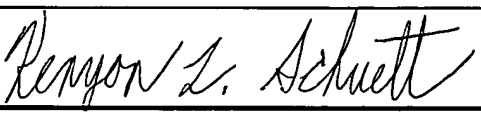
<tr><td>SIGNATURE</td><td colspan="2">  </td><td>DATE</td><td colspan="2">January 2, 2004</td></tr>
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